

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,177	12/17/2001	Clemence K. Darney	MCP-300	3307

27777 7590 02/10/2003

AUDLEY A. CIAMPORCERO JR.  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 02/10/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

10/023,177

Applicant(s)

DARTEY ET AL.

Examiner

Susan Tran

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-8 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-8 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Preliminary Amendment filed 12/17/01, Amendment filed 06/24/02, and Information Disclosure Statement filed 06/27/02.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 06/27/02 was filed after the mailing date of the Office Action on 03/19/02. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 5-8, and 13 rejected under 35 U.S.C. 102(a) as being anticipated by Sorkin, Jr. US 5,952,393.

Sorkin teaches a composition for reducing serum cholesterol comprising mixture of long chain aliphatic alcohols, e.g., policosanol and phytosterol; and binders, coating agents, diluents, emulsifiers, suspension agents, or stabilizers (column 2, lines 7-67). The mixture of policosanol and phytosterol can be incorporated into a soft gelatin capsule, or coated with tablet coating agent, including cellulose (example 1). Example

Art Unit: 1615

1 also discloses the weight ratio of the long chain aliphatic alcohol to the excipients (binders, coating agents, diluents, emulsifiers, suspension agents, or stabilizers).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mothes et al. US 5,961,707.

Mothes teaches alcohol-containing granules coated with waxes, cellulose, gelatin, lactose, or starches (column 3, lines 45-51). The alcohol-containing granules can be incorporated in dry soups, sauces, desserts, and beverages (column 3, lines 53-59). Although Mothes is silent as to the teaching of the intended use being claimed, e.g., use of the encapsulated alcohol to reduce cholesterol in a vertebrae, the intended use is inherent since Mothes obtains the same result from the use of encapsulated alcohol as additives useful in dry soups, sauces, desserts, and beverages.

Mothes is silent as to the teaching of long-chain alcohol. However, it would have been obvious for one of ordinary skill in this art to use any alcohol, which will include long-chain alcohol, fatty alcohol, or aliphatic alcohol. The expected result would be low dust content and free-flowing encapsulated alcohol granules useful in food products.

Art Unit: 1615

Claims 2-8, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mothes et al., in view of Cain et al. WO 98/47385.

Mothes is relied upon for the reason stated above. Mothes is silent as to the teaching of long-chain alcohol.

Cain teaches long-chain alcohol incorporated in food products, which can be used to provide simultaneously cholesterol-lowering properties (page 2, lines 14-24). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to modify Mothes' alcohol-encapsulated granules using the long-chain alcohol in view of the teaching of Cain. The reason for this modification is to obtain a food product containing long-chain alcohol encapsulated in polymer. The expected result would be a healthier food product containing encapsulated long-chain alcohol useful to lowering cholesterol.

Claims 5-8, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorkin, Jr. US 5,952,393.

Sorkin is relied upon for the reason stated above. In the case that the applicant can overcome the above 102(a) rejection, it is the position of the examiner that it would have been *prima facie* obvious for one of ordinary skill in this art to modify Sorkin's cholesterol lowering composition to obtain the claimed invention, because Sorkin teaches the advantageous results in the use of long chain aliphatic alcohols for the same purpose, e.g., for lowering serum cholesterol levels in human (column 2, lines 7-15).

***Response to Arguments***

Applicant's arguments filed 06/24/02 have been fully considered but they are not persuasive. Nonetheless, the 102(b) rejections by Mothes et al. US 5,961,707 and by Cain et al. WO 98/47385 have been withdrawn.

Applicant indicated that claim 1 has been canceled in the 12/17/01 Preliminary Amendment, however, in the Office Action dated 03/19/02, the Examiner inadvertently included claim 1 in the rejections, and therefore, it is requested to withdraw the rejections. Applicant's request has been fully considered but is not persuasive for the following reasons: (1) claim 1 was inadvertently included in the rejections; (2) the limitation of claim 1 has been incorporated into claim 5 in the 12/17/01 Preliminary Amendment; (3) the rejections did not pertain to claim 1 alone, but including claim 5 as a generic claim according to the Preliminary Amendment filed 12/17/01. For the above reasons, the examiner maintains the original 103(a) rejections.

It appears that applicant has accidentally traversed the 102(b) rejection by Mothes et al. US 5,961,707 (on page 4), but the intention is for Cain et al. WO 98/47385?

Applicant argues that Cain does not disclose long chain alcohol encapsulated in wax. The argument is persuasive, and therefore, the 102(b) rejection has been withdrawn. Nonetheless, Cain does teach long chain alcohol (component c) is being incorporated in a fat-emulsion (see abstract, and page 4, lines 1-21).

Art Unit: 1615

Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mothes et al. US 5,961,707.

Applicant argues that Mothes does not disclose the claimed long chain alcohol since Mothes defined ethanol as being the alcohol (column 1, lines 6-9). Applicant further alleged that the rejection is based on hindsight combination of components selectively. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Mothes in column 3, lines 40-44, discloses, in addition to alcohol and starch, natural and nature-identical flavourings can also be added to the granules. Accordingly, it is the position of the examiner that such language does suggest one of ordinary skill in the art to, by routine experimentation select a long chain (natural and nature-identical) compound that can also be added to the granules.

Claims 2-8, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mothes et al., in view of Cain et al. WO 98/47385.

Applicant argues that there is no evidence or reason to combine the two references. In response to applicant's argument that there is no suggestion to combine



Art Unit: 1615

the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Mothes discloses in addition to alcohol and starch, natural and nature-identical flavourings can also be added to the granules (column 3, lines 40-44). Cain discloses long chain alcohol is present in a number of natural products such as wheatgerm-wax, carnauba-wax, rice bran wax, and sugar cane wax (page 4, lines 1-12). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to modify Mothes' alcohol-containing granules using the natural products in view of the teachings of Cain with the expectation of at least similar result, because the references teach the advantageous results in the use of encapsulated alcohol in food products.

### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Laguna Granja et al., Thakkar et al., Bosc Yushi K.K., Raisio Yhtyma, and Sho et al. are cited as being of interest for the teachings of fatty alcohol compositions.

### ***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 06/27/02 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER T600